IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

SCHANEIQUA WRIGHT, Plaintiff, v. C. R. BARD, INC. and BARD PERIPHERAL VASCULAR, INC., Defendants.	§ § § § § § § § § §	Case No. 3:19-cv-2176-S

JOINT AMENDED PRETRIAL ORDER

TO THE HONORABLE UNITED STATES DISTRICT JUDGE:

COMES NOW Plaintiff Schaneiqua Marie Wright ("Marie Wright"), and Defendants C. R. Bard, Inc. ("C. R. Bard"), and Bard Peripheral Vascular, Inc. ("BPV") (C. R. Bard and BPV are collectively, "Bard") and submit the following Joint Pretrial Order in accordance with the Court's Second Amended Notice of Trial Setting and Order. (Doc. No. 152.)

A. SUMMARY OF THE CLAIMS AND DEFENSES OF EACH PARTY

This is a product liability action brought by Plaintiff relating to a prescription medical device called a Bard Recovery® Filter ("Filter"), which was implanted in Plaintiff. The Filter was designed and marketed by Defendant BPV and manufactured in a facility owned by Defendant C. R. Bard.

1. Plaintiff's Claims[1]

Plaintiff Marie Wright asserts the following claims arising as a result of having been implanted with Defendants' Recovery inferior vena cava filter: strict liability failure to warn;

[1] Plaintiff withdrew her claims for negligence *per se*, fraudulent concealment, manufacturing defect, breach of implied warranty, breach of express warranty, negligent misrepresentation, and fraudulent misrepresentation.

strict liability design defect; negligent design, negligent failure to warn, and gross negligence. Plaintiff also asserts a claim for punitive damages.

Plaintiff asserts fraudulent concealment and the discovery rule as defenses to Defendants' assertion that Plaintiff's claims are barred by the statute of limitations, not as independent causes of action.

2. **Defendants' Defenses**

Bard denies each of Plaintiff's claims. Specifically, Bard denies that the Filter or its warnings were defective under either a strict liability or negligence theory. Bard acted reasonably in all manners concerning the design, manufacture, and warnings of the Filter. Additionally, Bard denies that the Filter implanted in Plaintiff was defective and unreasonably dangerous. In that regard, the Filter's utility (specifically, the device's lifesaving ability to prevent blood clots from traveling to the heart or lungs) outweighed any risks. Bard further maintains that it provided legally adequate warnings concerning the Filter, particularly in light of the state of the art during the relevant time period. Bard also denies that any negligence, the product, and/or any alleged defect in the product or its warnings caused Plaintiff's injuries. Instead, Bard asserts various defenses, including, but not limited to, that there was no safer alternative design, and that the Filter was cleared pursuant to and in compliance with FDA regulations. Finally, Bard denies that Plaintiff is entitled to punitive damages. Bard maintains that -- aside from its contention that it is not liable to Plaintiff for any compensatory damages -- it has not engaged in fraud, malice, or gross negligence. Moreover, Plaintiff has not pleaded gross negligence and has withdrawn her claim for fraud. She has therefore not pleaded a cause of action to support a recovery of exemplary/punitive damages under Texas law.

B. STATEMENT OF STIPULATED FACTS

1. The following material facts are admitted by the parties and require no proof:

   a. The Defendants in this case are C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. ("BPV"). BPV is the wholly-owned subsidiary of C. R. Bard, Inc. Throughout this case, including in this pretrial order, the jury instructions and the verdict form, C. R. Bard, Inc. and BPV will be referred to collectively as "Bard" or "Defendants."

   b. The product that is the subject of this lawsuit is a Bard Recovery® IVC Filter ("Filter") that was designed, manufactured, marketed and sold by Bard;

   c. The Filter consists of a main cap to which twelve struts (six "arms" and six "legs") are attached**;**

   d. The Filter is constructed of a nickel-titanium alloy called Nitinol;

   e. The Filter is a medical device that is implanted in the inferior vena cava ("IVC"), the largest vein in the human body;

   f. The intended purpose of the Filter is to catch blood clots to prevent them from traveling to the heart or lungs;

   g. The predicate devices for the Recovery filter were the Simon Nitinol filter and the Titanium Greenfield Vena Cava Filter.

   h. Defendants stopped selling the Recovery filter in September 2005 at the time Defendants began selling the G2 filter.

   i. Brooke Gillette was employed by Defendants and was the territory manager responsible for the territory including Methodist Medical Center Dallas, which is where Plaintiff's filter was implanted.

   j. At the time of sale of the Bard Recovery filter that was implanted into Plaintiff, Jason Greer was employed by Defendants and was Brooke Gillette's supervisor.

   k. Plaintiff was under the care of Dr. Dirk Rodriguez who referred Plaintiff to Dr. Kenneth Kollmeyer, a vascular surgeon, to implant an IVC filter into Plaintiff prior to Plaintiff undergoing bariatric surgery to treat Plaintiff's morbid obesity.

   l. Dr. Kollmeyer read the Recovery Instructions for Use.

   m. At the time of Plaintiff's implantation, the Bard Simon Nitinol Filter was available on the market for implantation as a permanent IVC filter.

n. On July 5, 2005, Dr. Kenneth Kollmeyer implanted a Recovery Filter in Plaintiff's inferior vena cava.

o. On January 21, 2018, Plaintiff was found to have blood clots in her lungs.

p. Plaintiff's filter remains implanted in her inferior vena cava; however, the filter has fractured, and one piece is in her heart and another is in her lungs.

2. The following material facts, although not admitted, will not be contested at trial by evidence to the contrary:

a. Plaintiff is not seeking to recover past or future lost wages or loss of earning capacity as part of her damages.

3. The following issues of law are uncontested and stipulated to by the parties:

a. Plaintiff's claims and Bard's defenses are governed by Texas substantive law for Plaintiff's compensatory damages, but the parties do not agree as to the law applicable to Plaintiff's punitive damages claim.

b. The law enumerated in any jury instructions stipulated to by the parties.

c. The parties have stipulated on various evidentiary issues that would have otherwise been the subject of a motion *in limine*, and a stipulation memorializing those agreements has been filed on the docket (Doc. 144, attached as Exhibit A).

d. The parties further stipulate that they will not comment on, refer to, introduce, or attempt to elicit testimony or evidence of, or argue in the presence of the jury, whether directly or indirectly, including during voir dire, except as noted below, any of the following:

i. Dr. Frederick Rodgers' deposition designations regarding being a defense expert.

To the extent the Plaintiff designates testimony from Defendants' withdrawn expert, Dr. Frederick Rodgers, Plaintiff will remove designations of any testimony that refers, references, or implies that he was Defendants' expert.

ii. Dr. Krishna Kandarpa's Deposition Designations regarding Exhibit 7.

Testimony by Dr. Krishna Kandarpa regarding Exhibit 7 to his deposition, including specifically the following

pages/lines of his deposition: 82:3-91:7; 138:18-138:22; 155:23-162:1; 173:22-174:6; 174:24-175:9, and 212:19-213:13. The parties further agree that Exhibit No. 7 to Dr. Kandarpa's deposition is not to be shown during the presentation to the jury. The parties dispute whether page/lines 138:23-140:17 relate to Exhibit 7.

iii. Any reference to the July 13, 2015, FDA Warning Letter issued to Bard ("Warning Letter").

The parties agree that they will not make any reference, solicit testimony, or seek to introduce at trial evidence concerning Topics 1, 2, 4, 5, 6, 7, and 8 of the Warning Letter. The parties further agree that they will not make any reference, solicit testimony, or seek to introduce evidence concerning Topic 3 of the Warning Letter in the presence of the jury without first raising the issue with the Court outside the presence of the jury.

The Plaintiff's decision not to introduce evidence or solicit testimony on topics 1, 2, and 4 – 8 from the FDA Warning Letter is for purposes of this case only. Plaintiff's agreement to this stipulation in this case is not to be used in other cases to support a motion *in limine* where the plaintiff has not made a similar agreement.

C. LIST OF CONTESTED ISSUES OF FACT

Plaintiff's List of Contested Issues of Fact

1. Bard obtained clearance to market the Recovery filter by representing to the FDA that the Recovery filter was substantially equivalent to the Simon Nitinol filter with respect to safety.

2. It was important to Dr. Kollmeyer when making his risk/benefit determination to use a medical device to know the frequency with which complications occur for the device and how this compares to other devices on the market.

3. Dr. Kollmeyer relied on Bard to provide him with truthful and accurate information regarding the safety of the Recovery filter, including rates of adverse events and

complications because this information would have impacted his choice of filter for his patients.

4. Bard did not disclose to Dr. Kollmeyer or Dr. Rodriguez that the Recovery filter was experiencing higher rates of failure than competitor devices, with respect to bariatric patients or patients as a whole.

5. Bard did not disclose to Dr. Kollmeyer or Dr. Rodriguez that there had been deaths associated with use of the Recovery filter in bariatric patients.

6. Defendants' sales representative, Brooke Gillette marketed the Recovery inferior vena cava filter to Dr. Kollmeyer as superior to other filters, as she had been instructed to do by Defendants.

7. Defendants' sales representative, Brooke Gillette marketed the Recovery inferior vena cava filter to Dr. Kollmeyer for implantation into patients prior to bariatric surgery.

8. Prior to Plaintiff's implantation, Bard was aware of the following facts relating to the Recovery filter:

- In Bard's sole clinical study for the Recovery filter, the filter in one of the 32 study patients fractured twice. After the fractures were reported, the Canadian Institutional Review Board suspended the study. Additional adverse events in this study included two tilted filters, one migration, and one perforation of the IVC.

- Bard's 510(k) applications for the Recovery did not disclose that filters at the low end of the leg span specification only met the migration resistance test when the hooks were engaged, but that those hooks were not always engaged. The failure of Recovery anchor hooks to engage was a marked difference from the SNF.

- Comparative bench testing for migration resistance conducted in March 2004 demonstrated that the Recovery filter: (a) performed worse than the SNF at every caval diameter, (b) performed worse than almost all competitor devices at every caval diameter, and (c) failed Bard's own performance threshold for resistance at 28 mm.

- Two months after full market release of the Recovery, Bard national sales training manager stated: "Tilt resistance should probably be downplayed." Its marketing director acknowledged, "We knew very little about the long-term clinical performance of this device when we launched it. After a year of commercialization, there are still many questions that need to be answered."

- In the first 12 months after full market release there were seven deaths resulting from migration of the Recovery filter to patients' hearts.

- By April 2004, Bard knew that the Recovery filter was designed in a way that did not account for how the IVC actually behaved.

- In the midst of the migration deaths from the Recovery filter, Bard initiated a Crisis Communication Plan which included a messaging instruction that "[c]omparison with other filters is problematic in many ways and we should avoid/downplay this as much as possible. When pressed, we simply paraphrase … that estimates based on the available data suggest that there is no significant difference in the rates of these complications between any of the devices currently marketed in the U.S., including the Recovery device."

- By May 2004, Bard determined that, based on complications, "[a]t a 95% confidence, there IS a significant difference between Recovery, Gunther Tulip, Bird's Nest and SNF."

- By July 9, 2004, Bard determined that the Recovery had a fracture rate that was tens of times higher than other filters on the market.

- By September 2, 2004, Bard knew of 32 Recovery filter fractures. Of those 32, nine fragments had traveled to the heart or lungs of patients, including three open heart surgeries to retrieve fragments.

- In a December 9, 2004 Remedial Action Plan, the Division Investigation Team ("DIT", which includes three Vice-Presidents of Bard Peripheral Vascular ("BPV") along with other executives) concluded that:
    - "The bariatric patient population is highest risk patient population presently receiving the RNF [Recovery]."
    - "DIT believes that BPV data is compelling as to sub-population of bariatric patients."; and
    - "Reducing number of bariatric patients treated will reasonably reduce number of migration-related complications."

- By December 2004, Bard determined that the Recovery filter had rates of complications as compared to all other filters, including the SNF, as follows:
    - for deaths, 4.6 times higher;
    - for migrations, 4.4 times;
    - for IVC perforations, 4.1 times higher; and
    - for fractures, 5.3 higher times higher.

  Bard concluded that "[t]hese differences were all statistically significant."

- In January 2005, Bard's internal analysis revealed that "the data and [a consultant's] analysis provided two significant signals that further investigation particularly in relation to migration and fracture is urgently warranted."

- According to Bard's current Quality Engineering Manager for New Product Development, Natalie Wong, the Recovery was worse than the SNF with regard to filter-related deaths and filter fracture.

- On August 3, 2005, Bard's VP of Regulatory/Science reported the following comparison of the Recovery versus the SNF: 4500% greater rate of Recovery migrations; 16 deaths involving Recovery versus zero for SNF; Recovery deaths consisted of 11 from migrations of the device to the heart and five from pulmonary emboli the Recovery was intended to prevent; Bard also reported there were 68 Recovery fractures: 25 with metal struts embolizing to the heart or lungs and 4 requiring surgery to remove.

9. Prior to Dr. Kollmeyer's implantation of the Recovery filter into Plaintiff, Bard had not warned Dr. Kollmeyer or Dr. Rodriguez that the Recovery filter had a higher risk of complications than its competitor's devices and the Bard Simon Nitinol Filter.

10. Prior to Dr. Kollmeyer's implantation of the Recovery filter into Plaintiff, Bard had not warned Plaintiff that the Recovery filter had a higher risk of complications than its competitor's devices and the Bard Simon Nitinol Filter.

11. Bard's instructions for use ("IFU") that accompanied the Recovery filter that was implanted into Plaintiff did not include warnings that its filters fractured, migrated, and perforated patients' IVCs at rates significantly higher than competitor IVC filters or the Bard Simon Nitinol Filter.

12. Bard did not disclose that the Recovery filter causes an unreasonable risk of serious injury and death.

13. Plaintiff's Recovery filter has fractured, struts have embolized to her heart and lungs, and struts have perforated Plaintiff's inferior vena cava.

14. Plaintiff's Recovery filter caused her to suffer a pulmonary embolism.

15. Plaintiff has been advised by her treating physicians that it is too dangerous to have her Recovery filter removed.

16. Plaintiff's treating physicians have prescribed her with lifetime anticoagulation due to the presence of her Recovery filter in her body, to avoid another pulmonary embolism.

17. The presence of the Recovery filter in her IVC and struts in her heart and lungs, combined with the need for anticoagulation, has interfered with Plaintiff being able to obtain other necessary heath care, including a gynecological procedure.

18. The Bard Simon Nitinol Filter is a safer alternative device to the Recovery filter.

19. Warnings regarding risks and complications of the Recovery device were not adequately conveyed by Defendants to Dr. Kollmeyer or Dr. Rodriguez.

20. When in the exercise of reasonable care and diligence, Plaintiff should have discovered Plaintiff's injury and that it was likely caused by Bard's defective product or negligence.

21. Whether Defendants made fraudulent misrepresentations or concealed facts and prevented Plaintiff from discovering Plaintiff's causes of action against Defendants.

22. Was there a defect in the warnings at the time the Bard Recovery Inferior Vena Cava Filter left the possession of Bard and if so, was that defect a producing cause of the injuries, if any, to Plaintiff?

23. Was there a design defect in the Bard Recovery Inferior Vena Cava Filter at the time it left the possession of Bard and if so, was that defect a producing cause of the injuries, if any, to Plaintiff?

24. Was Bard negligent in designing or warning regarding use of the Bard Recovery Inferior Vena Cava Filter at the time it left Bard, and if so, was that negligence, if any, a proximate cause of the injuries, if any, to Plaintiff?

25. Whether Plaintiff's filter can be safely removed.

26. Whether Plaintiff has been injured and incurred damages caused by Defendants and if so, appropriate compensation for those damages.

27. If Texas law applies to Plaintiff's punitive damage claim, were Bard's acts or omissions grossly negligent, as defined under Texas law as follows:

"Gross negligence" means an act or omission by Bard,

a. which when viewed objectively from the standpoint of Bard at the time of its occurrence involves an extreme degree of risk, considering the probability and magnitude of the potential harm to others; and

b. of which Bard has actual, subjective awareness of the risk involved, but nevertheless proceeds with conscious indifference to the rights, safety, or welfare of others.

28. If Texas law applies to Plaintiff's punitive damage claim, were Bard's acts or omissions fraud or a misrepresentation, as defined under Texas law, as follows:

"Fraud" occurs when

a. a party makes a material misrepresentation, and

b. the misrepresentation is made with knowledge of its falsity or made recklessly without any knowledge of the truth and as a positive assertion, and

c. the misrepresentation is made with the intention that it should be acted on by the other party, or his or her surgeon, and

d. the other party, or his or her surgeon, relies on the misrepresentation and thereby the other party suffers injury.

"Fraud" also occurs when

a. a party fails to disclose a material fact within the knowledge of that party, and

b. the party knows that the other party, or his or her surgeon, is ignorant of the fact and does not have an equal opportunity to discover the truth, and

c. the party intends to induce the other party, or his or her surgeon, to take some action by failing to disclose the fact, and

d. the other party suffers injury as a result of acting, or as a result of his or her surgeon acting, without knowledge of the undisclosed fact.

29. If Arizona law applies to the punitive damage issue, was Bard "'aware of and consciously disregard[ed] a substantial and unjustifiable risk that' significant harm would occur" to bariatric patients like Plaintiff.

30. If Arizona law applies to the punitive damage issue, including section 12-689 of the Arizona Revised Statutes, enacted May 11, 2012, did the FDA determine that Bard violated applicable regulations requiring Bard to report adverse events to the FDA pertaining to the risks of harm for Bard's IVC filters, establishing an exemption to Bard's immunity under section 12-689?

Defendants' List of Contested Issues of Fact

1. **Design Defect:** Whether the filter implanted in Plaintiff had a design defect.

   a. Defendants' Contention: To establish a design defect, Plaintiff must prove that "'(1) the product was defectively designed so as to render it unreasonably dangerous; (2) a safer alternative design existed; and (3) the defect was a producing cause of the injury for which the plaintiff seeks recovery.' Texas law defines a safer alternative design as one that 'would have prevented or significantly reduced the risk of the claimant's personal injury ... without substantially impairing the product's utility.' Consistent with this risk-utility framework, a plaintiff 'must show the safety benefits from [the] proposed design are foreseeably greater than the resulting costs, including any diminished usefulness or diminished safety.' The Texas Supreme Court and intermediate appellate courts have held that a 'substantially different product' cannot constitute a safer alternative design." *In re DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prod. Liab. Litig.*, 888 F.3d 753, 765–66 (5th Cir. 2018). Defendants deny that there is evidence that (1) a safer alternative design existed, (2) it would have prevented or significantly reduced the risk of Plaintiff's personal injury without substantially impairing the Filter's utility, and (3) the alternative design was economically and technologically feasible at the time the Filter left the control of Bard by the application of existing or reasonably achievable scientific knowledge. Defendants further contend that *Restatement (Second) of Torts* § 402A, comment k, applies to

Plaintiff's claim, such that the Filter "cannot be found unreasonably dangerous and a seller cannot be held strictly liable where the [Filter is] accompanied by an adequate warning." *McKay v. Novartis Pharm. Corp.*, 934 F. Supp. 2d 898, 910 (W.D. Tex. 2013) (internal quote omitted), *aff'd*, 751 F.3d 694 (5th Cir. 2014); Tex. Civ. Prac. & Rem. Code § 82.008; *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 164-165 (Tex. 2012).

2. **Design Defect – Proximate Cause:** Whether a design defect of the Filter was the proximate cause of Plaintiff's injuries and damages.

   a. Defendants' Contention: Defendants deny that any alleged design defect in the Filter caused or contributed to Plainitff's alleged injuries;

3. **Negligent Design:** Whether Bard was negligent in the design of the Filter.

   a. Defendants' Contention: Defendants contend that Plaintiff's negligence design claim fails for the same reasons her strict liability design defect claim fails. *Gen. Motors Corp. v. Paiz*, No. 05-98-01340-CV, 2000 WL 1751096, at *4 (Tex. App.--Dallas Nov. 29, 2000, no pet.) ("[B]oth negligence and strict liability for defective design require proof of a defect in the product….All Paiz's evidence supported one design defect. Her theory was that an unreasonably dangerous seat caused her injuries and that this single defect existed because GM did not adopt a safer alternative seat design. Therefore, the defect at issue in both the strict liability and negligence theories is functionally identical.").

4. **Negligent Design – Proximate Cause:** Whether a design defect of the Filter was the proximate cause of Plaintiff's injuries and damages.

   a. Defendants' Contention: Defendants deny that any alleged design defect in the Filter proximately caused Plaintiff's injuries;

5. **Warning Defect:** Whether Bard failed to adequately warn of the risk of harm arising from the use of the Filter.

   a. Defendants' Contention: Defendants deny that its warnings were not adequate. They warned of the very conditions Plaintiff alleges occurred in this case. Defendants also contend that, under the learned intermediary rule, any duty to warn ran to the implanting physician, rather than to the plaintiff herself. *See Ebel v. Eli Lilly & Co.*, 536 F. Supp. 2d 767, 773 (S.D. Tex. 2008) *aff'd sub nom. Ebel v. Eli Lilly & Co.*, 321 F. App'x 350 (5th Cir. 2009) (applying Texas law) ("Where the crux of the suit is based on a failure to adequately warn, the learned intermediary doctrine may apply to strict liability, negligence, misrepresentation, and breach of warranty claims."). Further, the implanting physician in this case testified that the IFU adequately conveyed the risks of the precise complications that Plaintiff experienced.

6. **Warning Defect – Proximate Cause:** Whether a warning defect was the proximate cause of Plaintiff's injuries and damages.

   a. Defendants' Contention: Defendants deny that any alleged warning defect in the Filter proximately caused Plaintiff's injuries. Plaintiff's implanting physician testified that nothing Plaintiff's counsel showed or discussed with him would have changed his decision to treat Plaintiff with the Filter. Thus, Plaintiff has no evidence that "a proper warning would have changed the decision of the treating physician." *Ackermann v. Wyeth Pharm.*, 526 F.3d 203, 208 (5th Cir. 2008) (quoting *Dyer v. Danek Med., Inc.*, 115 F. Supp. 2d 732, 741 (N.D. Tex. 2000)). Further, the implanting physician testified that he was independently aware of the risks. *Dyer*, 115 F. Supp. 2d at 741. As a result, any alleged inadequacy in Bard's warning was not a cause of Plaintiff's injuries as a matter of law.

7. **Negligent Failure to Warn:** Whether Bard was negligent in its warning of the risk of harm arising from the use of the Filter.

   a. Defendants Contention: Defendants deny that they were negligent in providing the warnings about the risks of the filter. Defendants also contend that, under the learned intermediary rule, any duty to warn ran to the implanting physician, rather than to the plaintiff herself. *See Ebel v. Eli Lilly & Co.*, 536 F. Supp. 2d 767, 773 (S.D. Tex. 2008) *aff'd sub nom. Ebel v. Eli Lilly & Co.*, 321 F. App'x 350 (5th Cir. 2009) (applying Texas law) ("Where the crux of the suit is based on a failure to adequately warn, the learned intermediary doctrine may apply to strict liability, negligence,

misrepresentation, and breach of warranty claims."). Further the implanting physician testified that he was independently aware of the risks, and the IFU adequately conveyed the risks of the precise complications that Plaintiff experienced. As a result, any alleged inadequacy in Bard's warning was not a cause of Plaintiff's injuries as a matter of law.

8. **Negligent Failure to Warn – Proximate Cause:** Whether a warning defect was the proximate cause of Plaintiff's injuries and damages.

   a. Defendant's Contention: Defendants deny that any alleged warning defect in the Filter proximately caused Plaintiff's injuries. Plaintiff's implanting physician testified that nothing Plaintiff's counsel showed or discussed with him would have changed his decision to treat Plaintiff with the Filter. Thus, Plaintiff has no evidence that "a proper warning would have changed the decision of the treating physician." *Ackermann v. Wyeth Pharm.*, 526 F.3d 203, 208 (5th Cir. 2008) (quoting *Dyer v. Danek Med., Inc.*, 115 F. Supp. 2d 732, 741 (N.D. Tex. 2000)). Further, the implanting physician testified that he was independently aware of the risks. *Dyer*, 115 F. Supp. 2d at 741.

9. **Compensatory Damages:** Whether Plaintiff is entitled to damages and, if so, the amount of the damages.

   a. Defendant's Contention: Defendants contend that no doctor has specifically attributed any of the symptoms that Plaintiff has allegedly experienced to the filter, and Plaintiff is not entitled to recover compensatory damages.

10. **Punitive Damages:** Whether Plaintiff is entitled to damages and, if so, the amount of the damages.

    a. Defendant's Contention: Defendants deny that Plaintiffs are entitled to recover punitive damages. Texas choice-of-law rules apply, and should be analyzed on an issue-by-issue basis. *Spence v. Glock, GES.m.b.H*, 227 F.3d 308, 312 (5th Cir. 2000) (applying Texas choice-of-law rules and reversing the district court, noting that "[i]f the district court had performed a proper choice of law analysis, it likely would not have found Georgia law controlling on the tort issues in this nationwide class action….The place where the conduct causing the injury occurred is more likely to be Austria than Georgia, at least for the non-fraud claims."). Because Arizona has the most significant relationship to Plaintiff's claim for punitive damages, Arizona statute § 12-689 should apply to Plaintiff's claim. Other courts applying the same test that Texas choice-of-law requires concluded that Arizona law should apply. *See e.g., Peterson v. C R Bard Inc.*, No. 3:19-CV-01701-MO, 2021 WL 799305, at *7 (D. Or. Mar. 2, 2021) ("The Bard Defendants' alleged misconduct began in Arizona and proliferated from Arizona. Arizona law should determine

whether and to what extent they should be punished and deterred form future wrongdoing."); *Ocasio v. C.R. Bard, Inc.*, No. 8:13-CV-1962-T-36AEP, 2020 WL 3288026, at *6 (M.D. Fla. June 18, 2020) (finding no conflict between Florida and Arizona law because "[p]ursuant to either Florida or Arizona law, Defendants cannot be held liable for punitive damages in this case.")

Under that Arizona statute, Plaintiff's punitive damages claim is barred. *McMahill v C R Bard Inc*, No. CV 2017-000927, 2019 WL 4899720, at *4 (Ariz. Super. July 23, 2019) (finding that the "undisputed evidence shows that the Meridian filter received clearance from the FDA. As a result, the statute bars plaintiff's claim for punitive damages.").

Even if Texas law applies to Plaintiff's punitive damages claim, Plaintiff has not pleaded gross negligence and has withdrawn her claim for fraud. Plaintiff cannot prove by clear and convincing evidence that the harm with respect to which the plaintiff seeks recovery results from "(1) fraud; (2) malice; or (3) gross negligence." Tex. Civ. Prac. & Rem. Code § 41.003(a), (b).

11. **Discovery Rule:** When Plaintiff discovered, or in the exercise or reasonable diligence should have discovered, that she suffered an injury related to her medical device.

12. **Failure to Mitigate Damages:** Whether Plaintiff's damages should be reduced for failure to mitigate her damages. PJC 28.9; *Nabors Well Servs., Ltd. v. Romero*, 456 S.W.3d 553, 564 (Tex. 2015) ("A plaintiff's post-occurrence failure to mitigate his damages operates as a reduction of his damages award…."); *Hygeia Dairy Co. v. Gonzalez*, 994 S.W.2d 220, 224 (Tex. App. 1999) ("If raised by the pleadings and evidence, and if the complaining party submitted an instruction in substantially correct form, failure to submit an instruction on the duty to mitigate is reversible error.").

D. LIST OF CONTESTED ISSUES OF LAW

1. **Contested issues of law in the case as agreed upon by the parties**.

   a. The issues of law raised by the parties' motions *in limine*;

   b. The issues of law raised by Plaintiff at trial;

   c. The issues of law raised by Defendants at trial, including whether Plaintiff's claims are barred by the statute of limitations, and whether Arizona law applies to Plaintiff's punitive damages claim;

2. **Other contested issues of law in the case**:

a. **Whether Bard's compliance with FDA's 510(k) process creates a rebuttable presumption of non-liability pursuant to Texas Civil Practice and Remedies Code § 82.008, and whether Plaintiff has rebutted that presumption.**

i. Defendants' Contention: Defendants maintain, consistent with the decisions of multiple other federal courts, that Arizona law should apply to Plaintiff's punitive damages claim. If, however, Texas law were to apply, Defendants contend that under sections (a) and (c), a rebuttable presumption of non-liability exists for the Filter. Under section (a), the Filter "complied with mandatory safety standards or regulations adopted and promulgated by the federal government, or an agency of the federal government, that were applicable to the product at the time of manufacture and that governed the product risk that allegedly caused harm." Tex. Civ. Prac. & Rem. Code § 82.008(a); *Wright v. Ford Motor Co.*, 508 F.3d 263, 268 (5th Cir. 2007). Under section (c), the Filter "was subject to pre-market licensing or approval by the federal government, or an agency of the federal government, that the manufacturer complied with all of the government's or agency's procedures and requirements with respect to pre-market licensing or approval, and that after full consideration of the product's risks and benefits the product was approved or licensed for sale by the government or agency." Tex. Civ. Prac. & Rem. Code § 82.008(c); *Robles v. C.R. Bard, Inc.*, No. 5:13-CV-250-C, 2015 WL 11120857, at *3 (N.D. Tex. Mar. 23, 2015). *See also, Nolen, v. C. R. Bard, Inc, et al.*, No. 3:19-CV-0799, 2021 WL 1264539, at *9 (M.D. Tenn. Apr. 6, 2021) (analyzing identical "approval or license" language in a Tennessee statute and finding "it seems clear that authorization to market a product pursuant to the § 510(k) process is, in fact, a form of 'approval.' Indeed, as Bard points out, the U.S. Supreme Court itself has referred to '§ 510(k) approval' in its opinions (citations omitted). Defendants contend that the presumption applies in either scenario, that the statutory exceptions to rebut the presumption are preempted. The two exceptions permit a plaintiff to rebut the presumption by showing (1) FDA regulations are "inadequate to protect the public from unreasonable risks of injury or damage," and (2) that Bard withheld or misrepresented information that was material or relevant to FDA's determination of substantial equivalence under the 510(k) process. However, the Fifth Circuit found that nearly identical exceptions were preempted. *Lofton v. McNeil Consumer & Specialty Pharm.*, 672 F.3d 372, 381 (5th Cir. 2012) (concluding that the nearly identical exception in "§ 82.007(b)(1) is a fraud-on-the-FDA provision analogous to the claim considered in *Buckman*," and therefore "is preempted by the FDCA unless the FDA itself finds fraud"). Even if the exceptions are not preempted, Plaintiff has not rebutted the presumption.

ii. Plaintiff's Contention: Section 82.008(a) only applies where: (1) the product is governed by mandatory safety regulations, and (2) the governing safety regulations deal with the same product risk that resulted in Plaintiff's harm. *See* Tex. Civ. Prac. & Rem. Code § 82.008(a). Section 82.008(a) does not apply because there were no mandatory safety regulations or standards governing the 510(k) substantial equivalence clearance of the Bard Recovery filter. Section 82.008(a) also does not apply because the Recovery filter was not subject to mandatory safety standards governing the particular risks of, *inter alia*, fracture, fragment embolization, perforation, and inability to safely retrieve that have caused Plaintiff harm. *See Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 761 (S.D. W.Va. 2014). The November 1999 guidance document issued by the FDA in connection with 510(k) review of IVC filters is not a directive issued by the FDA mandating controls related to safety and effectiveness. *Booker v. C.R. Bard, Inc.*, 969 F.3d 1067, 1075 (9th Cir. 2020) (in the context of discussing the November 1999 guidance document, holding that "the FDA has not imposed any requirements related to the design of that device [Bard's G2 filter] or how a device of that design should be labeled."); *In re Bard IVC Filters Prods. Liab. Litig.*, No. MDL 15-02641-PHX DGC, 2017 U.S. Dist. LEXIS 193824, at *22-24 (D. Ariz. Nov. 22, 2017). Likewise, the July 2014 Guidance issued in connection with 510(k) evaluation of substantial equivalence is merely "guidance" and does not mandate any particular course of action. The "General Controls" also do not constitute mandatory safety controls. Bard has not cited any specific course of action mandated by the General Controls because there is none. Thus, neither the Guidance documents nor the General Controls are sufficient to invoke any section of Section 82.008.

Section 82.008(c) provides a defense only *if* the product was subject to pre-marketing licensing or approval by the federal government or an agency of the federal government "after full consideration of the products risks and benefits." Tex. Civ. Prac. & Rem. Code Ann § 82.008(c) (emphasis added). The Recovery filter was "cleared" for marketing under the abbreviated 510(k) procedure and never "licensed" or "approved" by the FDA through the pre-market approval process. Because the 510(k) process relates to a medical device's equivalence to another preexisting device, it does not require "full consideration of the products' risks and benefits" as required for application of 82.008. *See* Tex. Civ. Prac. & Rem. Code Ann. § 82.008(c). The FDA specifically advises 510(k) applicants that issuance of a substantial equivalence determination clearing the device for marketing "does not mean that FDA has made a determination that your device complies with other requirements of the [FDCA]." Courts to consider the issue have almost unanimously held that Section 82.008(c) does not apply to a 510(k)-cleared medical device because

clearance through 510(k) notification does not constitute FDA 'approval' of the device. *See Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 761 (S.D. W.Va. 2014); *Johnson & Johnson & Ethicon, Inc. v. Batiste*, No. 05-14-00864-CV, 2015 Tex. App. LEXIS 11517 (Tex. App. Nov. 5, 2015); *Till v. X-Spine Sys., Inc.*, No. 3:15-cv-00532-M, 2015 U.S. Dist. LEXIS 82859, at *12-13 n.25 (N.D. Tex. June 24, 2015); *but see Robles v. C.R. Bard*, No. 5:13-cv-250-C, 2015 U.S. Dist. LEXIS 179824 (N.D. TX. March 23, 2015) at p. 6. Likewise, Courts have consistently held that the 510(k) process does not address product safety and efficacy. *See, e.g., Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323 (2008); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 498 (1996); *Kaiser v. Johnson & Johnson*, No. 18-2944, 2020 U.S. App. LEXIS 1174 at *23 (7th Cir. Jan. 14, 2020); *Eghnayem v. Boston Sci. Corp.*, 873 F.3d 1304 (11th Cir. 2017); *In re Bard IVC Filters Prod. Liab. Litig.*, No. CV-16-00782-PHX-DGC, 2018 WL 1256768, at *9 (D. Ariz. Mar. 12, 2018); *In re Bard IVC Filters Prod. Liab. Litig.*, 289 F. Supp. 3d 1045, 1049 (D. Ariz. 2018); *In re: Cook Medical, Inc., IVC Filters Marketing, Sales Practices and Prod. Liab. Litig. MDL 2570*, No. 1:14-ML-0257-RLY-TAB MDL 2570, Doc. 6541 at 3 (S.D. Ind. Sept. 26, 2017); *Lay v. DePuy Orthopaedics, Inc. (In re DePuy Orthopaedics, Inc. Pinnacle Hip Implant Prods. Liab. Litig.)*, 2014 U.S. Dist. LEXIS 97743 at *34-35 (N.D. Tex. 2014); *see also Funk v. Stryker Corp.*, 631 F.3d 777, 780 (5th Cir. 2011); *Reeves v. AcroMed Corp.*, 44 F.3d 300, 303 (5th Cir. 1995). The aberrant ruling in *Robles* is simply incorrect in finding that that "510(k) clearance is equivalent to 'approval' or 'licensing' the 510(k) process." *See Robles*, No. 5:13-CV-250-C, 2015 U.S. Dist. LEXIS 179824.

The 82.008(c) presumption can be rebutted if *either* of the following are shown: (1) the standards or procedures used in the particular pre-market approval or licensing process were inadequate to protect the public from unreasonable risks of injury or damage; *or*, (2) the manufacturer, before or after pre-market approval or licensing of the product, withheld from or misrepresented to the government or agency information that was material and relevant to the performance of the product and was causally related to the claimant's injury. If Section 82.008(c) applies, Plaintiff's evidence is sufficient to rebut the presumption under each exception. As a mere clearance with no mandatory controls as to safety and effectiveness, the 510(k) process is "inadequate to protect the public from unreasonable risks of injury or damage." Further, Bard represented that the Recovery filter was substantially equivalent to Bard's own Simon Nitinol Filter ("SNF") and withheld information and/or misrepresented that the Recovery was substantially equivalent to the SNF. The withheld information included some of the very risks suffered by Plaintiff, fracture, fragment embolization, and perforation, and presented unreasonable risks of injury, especially to the bariatric patient population, *i.e.*, patients like Ms. Wright. Preemption does not apply, and Bard has

pointed to no authority regarding the rebuttal sections of 82.008. *Lofton v. McNeil Consumer & Specialty Pharmaceuticals*, 672 F.3d 372, 376 (5th Cir. 2012) does not apply because *Lofton* arises from the application of 82.007 to prescription drugs where the product label had specifically been approved by the FDA, not cleared as is the case for a 510(k) device like the Recovery filter.

b. **Whether Comment k to Restatement (Second) of Torts § 402(A) applies to this case.**

i. Defendant's Contention: Defendants contend that Texas has adopted the *Restatement (Second) of Torts* § 402A, including comment k thereto. *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 164-165 (Tex. 2012). And under Texas law, comment k should apply to bar design defect claims, like Plaintiff's, involving prescription medical devices because they are unavoidably unsafe. *McKay v. Novartis Pharm. Corp.*, 934 F. Supp. 2d 898, 910 (W.D. Tex. 2013) (internal quote omitted), *aff'd*, 751 F.3d 694 (5th Cir. 2014).

ii. Plaintiff's Contention: Texas has not extended comment k to medical devices, either categorically or on a product-by-product basis. *Christopher v. DePuy Orthopaedics, Inc.*, 888 F.3d 753, 772 (5th Cir. 2018). Consistent with the majority of jurisdictions, the Fifth Circuit specifically declined to interpret Texas law as foreclosing all medical implant-based liability categorically via Comment k. *Id.*

In *Centocor*, the case relied upon by Defendant, the court stated, "Comment k to section 402A *may* provide a defense to a design defect claim, but it certainly does not absolve a manufacturer of its liability for completely failing to warn of a dangerous side effect." *See Centocor, Inc. v. Hamilton*, 310 S.W.3d 476, 516 (Tex. App. 2010), *reversed in part by Centocor, Inc. v. Hamilton*, 372 S.W.3d 140 (Tex. 2012). The *Centocor* court did not apply Comment k as represented by Defendant to preclude design defect claims. *McKay v. Novartis Pharm. Corp.*, 934 F. Supp. 2d 898, 910 (W.D. Tex. 2013) is similarly inapplicable.

Even if Comment k applies to medical device claims in Texas, Comment k is an affirmative defense. *See Mutual Pharmaceutical Co., Inc. v. Bartlett*, 133 S.Ct. 2466, 186 L.Ed.2d. 601 (2013); *LaBarre v. Bristol-Myers Squibb Co.*, 544 Fed. Appx. 120 (3rd Cir. 2013); *Scelta v. Boehringer Ingelheim Pharmaceuticals, Inc.*, 404 Fed. Appx. 92, 95 (8th Cir. 2010). Because Comment k is an affirmative defense, the burden is on Defendant to prove that the Recovery filter was incapable of being made safer as a matter of law. To prove this, Bard must show the design of the Recovery was as safe as the best available testing and research permitted, and there was no feasible alternative design which accomplished the product's purpose with a lesser risk. *Toner v. Lederle Labs., a Div. of Am. Cyanamid Co.*, 112 Idaho 328, 336–37, 732 P.2d 297, 305–06 (1987); *accord*, e.g., *Adams v. G.D. Searle & Co.*, 576 So. 2d 728, 732–33 (Fla. Dist. Ct. App. 1991); *West v. Searle & Co.*, 305 Ark. 33, 40–41, 806 S.W.2d 608, 612 (1991); *Bryant v. Hoffmann-La Roche, Inc.*, 262 Ga. App. 401, 404, 585 S.E.2d 723, 727 (2003); *Pollard v. Ashby*, 793 S.W.2d 394, 400 (Mo. Ct. App. 1990).

Bard cannot possibly demonstrate the Recovery is unavoidably unsafe as a matter of law because there exist alternative designs for IVC filters, including the predicate to the Recovery – Bard's Simon Nitinol Filter. *See Miller v. Stryker Instr.*, 2012 WL 1718825 (D. Ariz. Mar. 29, 2012); *Larsen v. Pacesetter Sys., Inc.*, 74 Haw. 1, 24–25, 837 P.2d 1273, 1286 (1992). Because there were other filters available at the time of Ms. Wright's implant, including filters manufactured by Bard, that had lower risks of fracture, fragment embolization, migration, perforation and death, Bard cannot be immune under Comment k.

c. **Whether under Texas law, Plaintiff can argue the Filter should not have been marketed based only on a particular class of patients.**

i. Defendant's Contention: Defendants contend that Texas law prevents Plaintiff from claiming that the Filter should not have been marketed based on its use only in certain situations or for particular sub-groups of patients, even if the plaintiff is a member of that particular sub-group of patients. The appropriate inquiry is whether the product should have been marketed overall. *Ethicon Endo-Surgery, Inc. v. Gillies*, 343 S.W.3d 205, 213 (Tex. App.—Dallas 2011, pet. denied) ("Simply stating that a product was defectively designed for use in certain situations and, therefore, should not have been marketed at all, does not establish a standard of ordinary care applicable to the marketing of the product for use in other situations…").

ii. Plaintiff's contention: Plaintiff is alleging that the Recovery was defective for use in bariatric and other applications. The Recovery is defectively designed and had inadequate warnings for all uses. Further, Bard's marketing outside of the purposes for which it was

cleared by the FDA, *i.e.*, off label for Bariatric surgery, was negligent and particularly egregious, and exposed Plaintiff to additional risks known to Bard, which is relevant to Plaintiff's negligence and punitive damages claims. To be clear, Plaintiff is alleging that Bard should have warned Plaintiff and her treating physician regarding the dangers known at the time to Bard with respect to use of the Recovery filter in morbidly obese patients prior to bariatric surgery, which is the use at issue here.

In *Gillies*, the plaintiff non-suited her design defect claim and proceeded on a claim for negligent marketing. *Gillies*, 343 S.W.3d at 209-11. On the negligent marketing claim, the court held that "stating that a product was defectively designed for use in certain situations and, therefore, should not have been marketed at all, does not establish a standard of ordinary care applicable to the marketing of the product *for use in other situations*." *Gillies*, 343 S.W.3d at 213 (emphasis added). "The court did not hold that a defective design claim requires a showing that the product is defective as to all persons who use it." *In re Ethicon, Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-MD-02327, 2014 U.S. Dist. LEXIS 15287, at *2569 (S.D. W. Va. Jan. 15, 2014) (referencing *Gillies*).

d. **Whether Plaintiff's claims are barred by the statute of limitations.**

i. Defendants' Contention: Defendants contend that Plaintiff's claims are barred by the statute of limitations. Tex. Civ. Prac. & Rem. Code § 16.003.

ii. Plaintiff's Contention: Plaintiff timely filed her claim within two years of when, in the exercise of reasonable care and diligence, she discovered her injury and that it was likely caused by the wrongful acts of another. *See Childs v. Haussecker*, 974 S.W.2d 40 (Tex. 1998).

Bard fraudulently concealed information that prevented Ms. Wright from discovering her cause of action any earlier than two years before her claim was filed. Fraudulent concealment applies when a defendant makes a fraudulent misrepresentation to or, when under a duty to disclose, conceals facts from the plaintiff and thereby prevents the plaintiff from discovering the cause of action against the defendant. *Butler v. Juno Therapeutics, Inc.*, No. H-18-898, 2019 U.S. Dist. LEXIS 104079, at *79–81 (S.D. Tex. June 21, 2019). Bard was aware that the bariatric patient population, including Ms. Wright, is the "highest risk patient population" that received the Recovery filter and recommended informing such

patients/physicians of such as far back as 2004 and again in 2006. However, Bard never went through with this, concealing this and other vital information from Ms. Wright and her physicians, preventing Ms. Wright from having the information necessary to discover her causes of action against Bard arising out of the defective design of the Recovery filter.

E. ESTIMATED LENGTH OF TRIAL

It is estimated that the trial of this case will take a total of 15 court days, but the parties understand that the Court intends to try the case in 2 weeks. If that is the Court's intention, Defendants believe that strict time limits will be necessary to ensure that they will have equal time to present their case.

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F. LIST OF ADDITIONAL MATTERS THAT MAY AID IN THE DISPOSITION OF THE CASE

1. **MDL No. 2641 and Law of the Case**.

a. Defendants' Contention: For the last six years, Bard's entire line of retrievable IVC filters has been the subject of a multidistrict litigation created before the Honorable David G. Campbell, in the District of Arizona, known as the *In Re: Bard IVC Filters Products Liability Litigation*, MDL 2641. Fact and expert discovery relevant to Plaintiff's case was developed in the MDL. For example, in the MDL, Bard produced millions of additional pages of documents, the plaintiffs conducted the depositions of dozens of additional corporate witnesses, the parties named and deposed numerous additional expert witnesses, and Judge Campbell ruled on many *Daubert* motions and motions *in limine* as part of the bellwether trials. The history of the MDL, extensive discovery, and summaries of Judge Campbell's rulings on generic discovery and evidentiary issues is detailed in a Suggestion of Remand and Transfer Order, attached hereto as Exhibit B. Bard believes that the "Key Legal and Evidentiary Rulings" that Judge Campbell details beginning on page 17 of that Order should be the law of the case with respect to each case that has been remanded from the MDL, including Plaintiff's case.[2] These rulings include federal preemption; privilege and work-product rulings; *Daubert* rulings concerning many experts that Plaintiff identifies on her witness list; motions *in limine* that bear on generic issues applicable to the

[2] *In re Welding Fume Prod. Liab. Litig.*, No. 1:03-CV-17000, 2010 WL 7699456, at *2 (N.D. Ohio June 4, 2010) ("[T]he law of the case doctrine, in this context, ensures that the transferor judge is not asked to re-plow ground already prepared by the MDL court for the efficient harvest of a verdict at trial."); *In re Zyprexa Prod. Liab. Litig.*, 467 F. Supp. 2d 256, 273 (E.D.N.Y. 2006) (under the law of the case doctrine, pre-remand orders of the transferee court "remain binding if the case is sent back to the transferor court."); *see also* Multi District Litigation Act, 28 U.S.C. § 1407 (intended to "promote the just and efficient conduct of [] actions" through "coordinated or consolidated pretrial proceedings").

remanded cases, including Plaintiff's case; and deposition designations of various Bard corporate and expert witnesses.[3]

a. Plaintiff's Contentions: Not all of the MDL rulings should be preserved under the law of the case doctrine. '"The law of the case doctrine requires that courts not revisit the determinations of an earlier court unless (i) the evidence on a subsequent trial was substantially different, (ii) controlling authority has since made a contrary decision of the law applicable to such issues, or (iii) the decision was clearly erroneous and would work . . . manifest injustice."' *McKay v. Novartis Pharm. Corp.*, 751 F.3d 694, 703 (5th Cir. 2014) quoting *In re Ford Motor Co*., 591 F.3d 406, 411 (5th Cir. 2009). Plaintiff contends the rulings of the MDL court on motions *in limine* on the following issues should be reconsidered as urged in Plaintiff's motions *in limine*, summarized here, as follows:

- The Surgeon General's 2008 Call to Action: In the *Hyde* bellwether trial, the Bard MDL Court denied a similar motion, ruling based on Wisconsin law that the Call to Action was relevant to the reasonableness of Bard's actions and to the risk-benefit analysis. Order *(Hyde)*, at 1, 4-6, *In re: Bard IVC Filters Products Liab. Lit*., No. MDL 15-02641-PHX-DGC (D. Ariz., Sept. 7, 2018), MDL ECF Doc. 12533 at 1, 4-6, attached as Exhibit C. This ruling should be reconsidered because Plaintiff Hyde was implanted with her Bard filter in 2011, after the 2008 Call to Action, thus the evidence is substantially different in this case, where the filter was implanted 3 years before the Call to Action was released.

- The MDL Court denied a motion to exclude reference to the efficacy of IVC filters and statistics of thrombi and pulmonary embolism. Order *(Booker)*, at 7, *In re: Bard IVC Filters Products Liab. Lit*., No. MDL 15-02641-PHX-DGC (D. Ariz., March 3, 2018), MDL ECF Doc. 10258 at 7, attached as Exhibit D. This ruling does not bar a ruling on Plaintiff's motion which is narrowly directed to *limine* references to the efficacy of IVC filters in the general population, as opposed to the bariatric population, and statistics of thrombi and pulmonary embolism and death in the general population. The MDL plaintiff, Ms. Booker, was implanted with a Bard G2 filter in 2007 prior to surgery to remove a cancerous surgical mass, not prior to bariatric surgery. Because this case involves substantially different facts, this court may grant the motion *in limine* in this case without violating the law of the case doctrine.

2. **Relevant MDL *Daubert* Orders**

a. Defendants' Contention: Plaintiff identified numerous expert witnesses who were disclosed in the MDL and who were the subject of *Daubert* rulings in the

[3] Bard believes that the majority of the deposition designations are generic in nature, and thus subject to Judge Campbell's rulings in the MDL.

MDL. Bard submits that the scope of these experts' testimony should be governed by the MDL *Daubert* orders as the law of the case:

- Sanjeeva Kalva, Thomas Kinney, and Anne Christine Roberts – MDL *Daubert* Order (MDL Doc. 9434), attached hereto as Exhibit E;
- Robert O. Ritchie, Ph.D. – MDL *Daubert* Order (MDL Doc. 10052), attached hereto as Exhibit F;
- Robert M. McMeeking – MDL *Daubert* Order (MDL Doc. 10051), attached hereto as Exhibit G;
- David Garcia, M.D. and Michael Streiff, M.D. – MDL *Daubert* Order (MDL Doc. 10072), attached hereto as Exhibit H;
- Mark J. Eisenberg, M.D. – MDL *Daubert* Order (MDL Doc. 9770), attached as Exhibit I;
- David Kessler, M.D., J.D. – MDL *Daubert* Order (MDL Doc. 9433), attached as Exhibit J;
- Suzanne Parisian, M.D. – *Id*., MDL *Daubert* Order (MDL Doc. 9433); and
- Rebecca Betensky, Ph.D. – MDL *Daubert* Order (MDL Doc. 9773), attached as Exhibit K.

b. Plaintiff's Contention: Defendant has identified expert witnesses who were disclosed in the MDL and who were the subject of *Daubert* rulings in the MDL. Plaintiff submits that the scope of these experts' testimony should be governed by the MDL *Daubert* orders as the law of the case:

- Christine L. Brauer, Ph.D. – MDL *Daubert* Order (MDL Doc. 10922), attached as Exhibit L.
- Clement J. Grassi, M.D., FSIR – MDL Daubert Orders (MDL Docs. 9991 and 10230), attached as Exhibits M and N.

3. **Dispute Regarding Order of Playing Deposition Designations**

a. Plaintiff's Contention: Plaintiff's contention, with which the Court agreed in the hearing held on August 7, 2020, is that if Plaintiff plays portions of a deposition in her case-in-chief, Bard may play its counter-designations, and Plaintiff may play her reply designations, if any, all during Plaintiff's case-in-

chief. That witness would then not be played in Bard's case-in-chief. If Plaintiff does not play a witness's testimony in her case-in-chief, Bard may play its affirmative designations in its case-in-chief, Plaintiff may play her counter-designations, and Bard may play its reply designations, if any, all during Bard's case-in-chief. This procedure is consistent with the ordinary course of a trial in which plaintiff conducts a direct examination, defendant conducts a cross examination, and plaintiff conducts a redirect examination, and is consistent with how deposition testimony has been presented in the Cook MDL bellwether trials. This procedure is of course subject to Fed. R. Civ. P. 106, a/k/a the rule of completeness, which in rare circumstances may require the introduction of certain testimony that ought to be considered at the same time.

b. Defendants' Contention: The deposition designations during the three bellwether trials that Judge Campbell conducted in the MDL were all played in the same manner that Bard is requesting here – that the designations from each deposition be played chronologically.[4] Defendants are aware of the Court's prior instruction that all of the parties' designations for a particular deposition will be played together, with the party calling the witness first playing their "direct," the opposing party then playing their "cross-examination", and then the offering party playing their "re-direct." Since the Court provided that guidance to the parties during the status conference on July 27, 2020, Plaintiff has taken a position which Defendants believe is manifestly unfair and contrary to controlling law. For those fact witnesses that both parties designated from, Plaintiff takes the position that Defendants will be precluded from playing their "affirmative" designations in the event that Plaintiff chooses to play the video. *I.e.*, the only portion of Defendants designations that will ever be played will be those designated as "counter-designations" to Plaintiff's "affirmative" designations. Defendants believe this is inconsistent with the case law below and not the result the Court intended.

Plaintiff is taking the position that her deposition designations must be played completely, and separately, from Bard's counter-designations. This will result in the deposition being played entirely out of order in a confusing, and at times, nonsensical manner. Such an approach would inevitably result in segments of a deposition being placed twice, as Defendants would have to reorient the jury to whatever issue is being discussed in order to provide the fair context for that issue. Federal Rule of Evidence 106, which codifies the common law Rule of Completeness, provides that "[i]f a party introduces all or part of a writing or recorded statement, an adverse party may require the introduction, *at that time*, of any other part—or any other writing or recorded statement—that in fairness ought to be considered at the same time."

[4] In *Peterson v. C R Bard Inc.*, No. 3:19-CV-01701-MO, (D. Or.), the only other federal court to rule on this issue in a remanded MDL case, rejected the same arguments made by the same plaintiffs' counsel as in this case. The court ruled that it will follow the same format established by Judge Campbell in the MDL in the trial to be commenced in early May 2021.

(emphasis added). The rule therefore permits the "contemporaneous" introduction of recorded statements which would be misleading when viewed alone. *United States v. Branch*, 91 F.3d 699, 727 (5th Cir. 1996). "The rule is based on two considerations. The first is the misleading impression created by taking matters out of context. The second is the inadequacy of repair work when delayed to a point later in the trial." U.S.C.S. Fed. R. Evid. 106, advisory committee notes.

The Rule of Completeness permits the contemporaneous admission of additional documents or testimony where they would be "relevant and helpful for purposes of providing background information," even where the document introduced by the opposing party was "not necessarily incomplete" without the addition. *Greener v. Cadle Co.*, 298 B.R. 82, 91 n.6 (N.D. Tex. 2003). Here, Bard's deposition designations in this case are relevant and helpful in this case because they are necessary to provide the fair context for any given testimony. For example, there are many examples in the parties' deposition designations of a witness's answer being cut-off mid-answer, with Plaintiff seeking to submit only a snippet of the answer. By way of another example, Defendants contend that neither party should be permitted to present testimony of a witness about a particular document without presenting, at the same time and in the proper order, the remainder of the witness's relevant testimony about that document. As the Fifth Circuit has explained, counter-designations are not a substitute for live cross-examination: "Only through *live* cross-examination can the fact-finder observe the demeanor of a witness, and assess his credibility. A cold transcript of a deposition is generally no substitute… FED. R. EVID. 106 seeks to relieve this tactical disadvantage by permitting an opposing party to combat an unquestioned 'cold transcript' at the moment of its introduction by entering into evidence the remainder." *United States v. Garcia*, 530 F.3d 348, 353 (5th Cir. 2008) (emphasis original) (citation omitted). As Defendants understand it, Plaintiff's proposal is contrary to these Fifth Circuit opinions. Defendants seek the very "contemporaneous" introduction of a recorded statement Rule 106 requires. *See Branch*, 91 F.3d at 727.

Furthermore, Federal Rule of Evidence 611 provides federal courts the discretion to "exercise reasonable control over the mode and order of … presenting evidence." In doing so, "objectivity and the appearance of neutrality" should be maintained; *Dartez v. Fibreboard Corp.*, 765 F.2d 456, 471 (5th Cir. 1985), and "efficiency" should not be sought "without regard to the consequences." *In re Propulsid Prod. Liab. Litig.*, No. 1355, 2000 WL 1880319, at *1 (E.D. La. Dec. 27, 2000). Thus, Federal Rule of Civil Procedure 32(a)(6), "Using Part of a Deposition" in court proceedings, provides that "[i]f a party offers in evidence only part of a deposition, an adverse party may require the offeror to introduce other parts that in fairness should be considered with the part introduced, and any party may itself introduce any other parts." *See also, Use of Part of a Deposition*, 8A Fed. Prac. & Proc. Civ. § 2148 (3d ed.) (noting that "reading only part [of a deposition] creates risks that the statement of the witness will be

misinterpreted by selective use of portions of the deposition testimony out of context or with qualifications of the testimony omitted" and Rule 32(a)(6) "provides a means for avoiding this danger") Here, principles of fairness and efficiency are both advanced by the contemporaneous introduction of both deposition designations. This is equally applicable to depositions without video which will be read to the jury.

The Fifth Circuit in *Huddleston v. Herman & MacLean* held that additional portions of deposition testimony were "improperly rejected" where Rule 106 called for their admission. *Id.* at 553. Moreover, under the identical Tex. R. Evid. 106, one Texas court reasoned that "the remedy" to an opposing party's introduction of testimony that was "not complete" was for the appellant to "introduce the unedited deposition or their own edited version." *Jones v. Colley*, 820 S.W.2d 863, 866 (Tex. App.--Texarkana 1991, writ denied). Bard seeks the very remedy prescribed for these circumstances.

Defendants continue to believe that the only resolution of this issue is to play each deposition once, with both parties' designations being played in chronological order. Particularly given the fact that the Court has indicated that the trials will be conducted in two weeks rather than three weeks, with efficiency being paramount, this approach appears to be the only practicable option that does not deprive either party of the right to present its evidence. Moreover, this chronological approach is the manner that was agreed upon by the plaintiffs and Defendants during each of the three bellwether trials in MDL No. 2641, with neither party disputing the fairness, efficiency, or propriety of presenting the deposition testimony in this manner. The overwhelming majority of depositions to be presented at trial are discovery depositions, not preservation depositions.

4. **Stipulation to Bifurcate Punitive Damages**

a. The parties stipulate to bifurcate the trial of this case pursuant to Rule 42(b) to avoid prejudice from introduction of Bard's net worth in the first phase of the trial, and Bard has filed an uncontested motion to bifurcate. Bard will request, and Plaintiff does not oppose, that the trial be conducted in two phases: determining liability, compensatory damages, and whether punitive damages should be awarded in the first phase of trial; and, if necessary, determining the amount of punitive damages in the second phase. The three bellwether trials that Judge Campbell conducted in the MDL were all bifurcated in the same manner Bard is requesting.

5. **Trial Logistics, Medical Records, and Reservation of Rights**

a. The parties have listed exhibits on their exhibit lists subject to pending motions *in limine* and other rulings by the Court. By listing exhibits, Bard

does do not contend that the exhibits are necessarily admissible and does not intend to waive any objection they have to the admissibility of the same.

b. The parties agree that a total of up to 25 exhibits per side that may have been inadvertently left off the exhibit list may be separately provided at least 24 hours in advance before any omitted exhibit is to be used at trial subject to objections on substantive grounds. Parties reserve the right to exceed 25 exhibits for good cause shown or as the court may allow.

c. Advance Notice of Exhibits:

i. The parties agree that neither party is waiving its right to use PowerPoints or drawings during trials by not including them on the exhibit list; the parties specifically reserve their right to raise evidentiary objections to the same during trial.

ii. Plaintiff's Contention: Plaintiff agrees to provide the opposing party with any animations or computerized simulations similar to animations 48 hours or more before they are to be used during opening or during witness examination.

iii. Bard's Contention: In the MDL trials, the parties exchanged a list of exhibits to be used with each witness (except exhibits used solely for impeachment) at least 24 hours before the witness was called to testify, and exchanged demonstrative exhibits, animations or computerized simulations, PowerPoints, and drawings 72 hours or more before they were to be used during opening or during witness examination. Bard submits that this will significantly promote efficiency during trial, particularly given the potential for witnesses to appear virtually, and is in the spirit of the Court's comments during the July 27, 2020, hearing regarding demonstratives that the parties not "bring something into court without the other side knowing with quite a bit advanced notice that it's coming." (Doc. 193 at 14:24 – 15:2.).

d. Advance Notice of Witnesses:

i. The parties agree that to promote the efficiency of the trial under the time limits, they will provide each other with the names of witnesses who will be called, whether appearing in-person, virtually, or by deposition, at least 48 hours in advance of the witness being called.

ii. Plaintiff's Contention:, Plaintiff agrees to provide final deposition designations and corresponding video cuts by 9 PM the night before the deposition is played.

iii. Defendant's Contention: Bard submits that both final deposition designations and corresponding video cuts be provided at least 24 hours

before the deposition is played in order to expedite trial and reduce the risk of last-minute technological issues.

e. The parties agree to the following procedures that might expedite trial to the extent possible: (a) presenting stipulated summaries of work history and professional background and qualifications of witnesses appearing by deposition rather than using deposition excerpts. The parties agree to meet and confer and at least 24 hours before a deposition is played to provide the proposed summary to opposing counsel for review and approval, although the parties are not obligated to use such summaries and may play the deposition testimony; (b) stipulations on authenticity and foundation; and (c) using the courtroom technology to expedite the presentation of evidence.

f. The parties stipulate that the Plaintiff's medical records and bills are authentic and satisfy the business records exception, but reserve all other available objections.

g. The parties wish to reserve the right to amend their deposition designations, counter-designations, and exhibit list, and objections to the same, based on the Court's rulings on all pending motions.

h. Invoke Rule of Evidence 615, but request that expert witnesses not be included in the exclusionary rule and thus be allowed to observe or review testimony.

6. **Confidentiality of Documents**

a. Defendants' Contention: Many of the documents listed as potential exhibits were produced by Defendants subject to a Protective Order. The Protective Order(s) does not specify how documents designated as confidential are to be used as exhibits at trial. Defendants raise this issue to preserve it and are prepared to address it during the Pretrial Conference. Until the exhibits are admitted, Defendants do not know which exhibits, if any, they need to move to seal. Defendants request that the exhibits be maintained by the Court reporter and not made available publicly throughout the trial and that Defendants be given a reasonable time after the conclusion of the trial to determine whether they intend to file a motion to seal, and that the Court set a briefing schedule for a post-trial briefing schedule on a motion to seal, if Defendants determine that they intend to move to seal any of the admitted exhibits.

b. Plaintiff's Contention: Plaintiff contends that any exhibit admitted into evidence is a public record. Generally, the public has a right of access to discovery materials. *See Ironclad, L.P. v. Poly-America, Inc.*, CIVIL ACTION NO. 3:98-CV-2600-P, 2000 U.S. Dist. LEXIS 10728, at *48 (N.D.

Tex. July 28, 2000). Further, there is a "strong presumption that all trial proceedings should be subject to scrutiny by the public." *United States v. Holy Land Found. For Relief & Dev.*, 624 F.3d 685, 690 (5th Cir. 2010). Thus, the district court must use caution when exercising its discretion to seal judicial records. *N. Cypress Med. Ctr. Operating Co. v. Cigna Healthcare*, 2015 WL 1069411, at *13 (5th Cir. Mar. 10, 2015) (internal quotations omitted); *Federal Sav. & Loan Ins. Corp. v. Blain*, 808 F.2d 395, 399 (5th Cir. 1987) ("The district court's discretion to seal the record of judicial proceedings is to be exercised charily."). Although upon a showing of good cause, a court may enter a protective order limiting the use of a trade secret or other confidential information, without specific information regarding the documents that Defendants seek to seal, Plaintiff cannot state a more specific position. *See* Fed. R. Civ. P. 26(c)(7). Regardless, Plaintiff anticipates opposing any motion to seal trial exhibits.

G. WHETHER THE CASE IS JURY OR NON-JURY TRIAL

This case is set to be tried as a jury trial.

Signed this 26th day of May, 2021.

HONORABLE KAREN GREN SCHOLER
UNITED STATES DISTRICT COURT JUDGE

CERTIFICATION

Prior to the date of submission of this Joint Pretrial Order, counsel all Parties personally conferred on numerous occasions to discuss this Order and the matters contained herein are agreed as indicated and submitted to the Court.

The Joint Pretrial Order is agreed upon and is hereby submitted to the Court for entry.

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing document has been filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all counsel of record on this 25th day of May, 2021.

/s/ Melissa Dorman Matthews